Message Text

UNCLASSIFIED

PAGE 01 STATE 048311

64
ORIGIN HEW-06

INFO OCT-01 AF-06 ARA-10 EUR-12 ISO-00 OES-05 /040 R

DRAFTED BY DHEW/FDA: JRWEINROTH, M.D.: AMS
APPROVED BY OES/APT/BMP: WJWALSH, III
DHEW/OIH: MACODDING
EUR/NE:KHSHIRLEY(INFO)
EUR/NE:SWORREL(INFO)
ARA/CAR:DCNORTON(INFO)
AF/S:FBCRUMP(INFO)
---------- 051093
P 272325Z FEB 76
FM SECSTATE WASHDC
TO AMEMBASSY BRUSSELS PRIORITY PRIORITY
AMEMBASSY KINGSTON PRIORITY
AMEMBASSY MEXICO PRIORITY
AMEMBASSY PRETORIA PRIORITY
AMCONSUL HAMILTON PRIORITY

UNCLAS STATE 048311

E.O. 11652: N/A

TAGS: OGEN, ETRD, TBIO, BD, BE, JM, MX, SF

SUBJECT: FDA ADVISORY - FAULTY MANUFACTURING PRACTICES AND POSSIBLE PRODUCT NON-STERILITY (RECALL NO. D-213-6, D-214-6 AND D-215-6)

1. FDA ADVISES THAT:

PRODUCT INVOLVED:

A. MARCAINE HCL 0.75 PERCENT (BRAND OF BUPIVACAINE HCL) WITH EPINEPHRINE 1:200,000 (BITARTRATE); WINTHROP LABORATORIES, DIV. OF STERLING DRUG, INC., NY, NY 10016; INJECTABLE; 5/30 ML. AMPULES PER BOX. (RECALL D-213-6)

B. MARCAINE HCL 0.5 PERCENT (BRAND OF BUPIVACAINE
UNCLASSIFIED

UNCLASSIFIED

PAGE 02 STATE 048311

HCL) WITH EPINEPHRINE 1:200,000 (BITARTRATE); WINTHROP

LABORATORIES, DIV. OF STERLING DRUG, INC., NY, NY
10016; INJECTABLE; 5/30 ML. AMPULES PER BOX; OR IN 50 ML.
VIALS. (RECALL D-214-6)

C. MARCAINE HCL 0.25 PERCENT (BRAND OF BUPIVACAINE HCL)
WITH EPINEPHRINE 1:200,000 (AS BITARTRATE); WINTHROP
LABORATORIES, DIV. OF STERLING DRUG, INC., NY, NY 10016;
INJECTABLE; 5/50 MM. AMPULES PER BOX; OR IN 50 MM. VIALS.
(RECALL D-215-6)

LOT NUMBERS:

ALL LOT NUMBERS ENDING IN "LA" THROUGH "LO" AND "NA"
THROUGH "NK".

A. AMPULES (D-213-6)

064KN
059LF
226NC
064NF
246NH
078NE (GOVERNMENT)

B. AMPULES (D-214-6)

057LF 138NF
058LF 139NF
065LK
042LO
092NA
225NC
088NE
137NF

VIALS (D-214-6)

511LK
464NA
349NF
UNCLASSIFIED

UNCLASSIFIED

PAGE 03 STATE 048311

370NE (GOVERNMENT)
065NF (GOVERNMENT)

C. AMPULES (D-215-6)

010LA
011LA
007LB

202NH

VIALS (D-215-6)

218NA
219NE
008NH
072NH (GOVERNMENT)
202NH (GOVERNMENT)
203NH (GOVERNMENT)

DISTRIBUTION: FROM 1/1/74 UNTIL 10/1/75

MANUFACTURER:

STERLING DRUG, INC.
33 RIVERSIDE AVE.
RENSSELAER, NY 12144

RECALLING FIRM:

A.
WINTHROP LABORATORIES
DIV. OF STERLING DRUG, INC.
90 PARK AVE.
NY, NY 10016

B.
WINTHROP PRODUCTS
90 PARK AVE.
NY, NY 10016

REASON FOR ADVISORY (RECALL:
UNCLASSIFIED

UNCLASSIFIED

PAGE 04 STATE 048311

THROUGH VARIOUS INSPECTION REPORTS AND AT CONFERENCES HELD WITH THE CORPORATION'S RESPONSIBLE OFFICIALS, FDA ALLEGED THAT THE PRODUCTS WERE NOT AND HAD NOT BEEN MANUFACTURED IN CONFORMANCE WITH CURRENT GOOD MANUFACTURING PRACTICE REGULATIONS AND THAT THERE WAS A QUESTION OF PRODUCT STERILITY. AFTER SEVERAL MORE MEETINGS AND IN-DEPTH REVIEWS OF BATCH RECORDS OF "STERILE" DRUG PRODUCTS, THE FIRM INSTITUTED A RECALL O THE INJECTABLE PRODUCTS INVOLVED.

2. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE BEEN INFORMED OF THE DETAIL OF THE RECALL AND IF THEY HAVE RECEIVED THE RCA GLOBAL CABLES SENT BY THE FIRM TO ALL FOREIGN DISTRIBUTORS ON

AN INDIVIDUAL BASIS CONCERNING THIS RECALL. POSTS MA
ALSO WISH TO CONTACT HOST COUNTRY DRUG CONTROL AUTHORIT
INFORMING THEM OF THE RECALL SO THAT THEY MAY TAKE SUCH
ACTIONS AS THEY DEEM APPROPRIATE.

3. FOREIGN CONSIGNEES AS FOLLOWS:

A. BERMUDA GENERAL AGENCY; HAMILTON, BERMUDA (0.5 PERCENT,
50 ML. VIALS)
B. DR. J. S. MUNGADIN, NEW YORK STERLING WINTHROP
CONTINENTAL SA, BRUSSELS, BELGIUM (0.25 PERCENT, 0.5
PERCENT AMPULE AND VIAL).
C. STERLING DRUG INTERNATIONAL LTD., JAMAICA, WI
(0.25 PERCENT, 0.5 PERCENT, 0.75 PERCENT AMPULES).
D. THE SIDNEY ROSS CO., MEXICO 18, DS, MEXICO (0.5
PERCENT AMPULE AND VIAL, 0.75 PERCENT AMPULE)
E. STERLING DRUG (SA) (PPY) LTD., NATO, REPUBLIC OF
SOUTH AFRICA (0.5 PERCENT AMPULE). INGERSOLL

UNCLASSIFIED

NNN

Message Attributes

Automatic Decaptioning: X
Capture Date: 01 JAN 1994
Channel Indicators: n/a
Current Classification: UNCLASSIFIED
Concepts: RECALLS, FOOD & DRUG REGULATIONS
Control Number: n/a
Copy: SINGLE
Draft Date: 27 FEB 1976
Decaption Date: 01 JAN 1960
Decaption Note:
Disposition Action: n/a
Disposition Approved on Date:
Disposition Authority: n/a
Disposition Case Number: n/a
Disposition Comment:
Disposition Date: 01 JAN 1960
Disposition Event:
Disposition History: n/a
Disposition Reason:
Disposition Remarks:
Document Number: 1976STATE048311
Document Source: CORE
Document Unique ID: 00
Drafter: JRWEINROTH, M.D.: AMS
Enclosure: n/a
Executive Order: N/A
Errors: N/A
Film Number: D760075-0675
From: STATE
Handling Restrictions: n/a
Image Path:
ISecure: 1
Legacy Key: link1976/newtext/t1976023/aaaaacdk.tel
Line Count: 189
Locator: TEXT ON-LINE, ON MICROFILM
Office: ORIGIN HEW
Original Classification: UNCLASSIFIED
Original Handling Restrictions: n/a
Original Previous Classification: n/a
Original Previous Handling Restrictions: n/a
Page Count: 4
Previous Channel Indicators: n/a
Previous Classification: n/a
Previous Handling Restrictions: n/a
Reference: n/a
Review Action: RELEASED, APPROVED
Review Authority: castelsl
Review Comment: n/a
Review Content Flags:
Review Date: 19 JUL 2004
Review Event:
Review Exemptions: n/a
Review History: RELEASED <19 JUL 2004 by schwenja>; APPROVED <08 SEP 2004 by castelsl>
Review Markings:

Margaret P. Grafeld
Declassified/Released
US Department of State
EO Systematic Review
04 MAY 2006

Review Media Identifier:
Review Referrals: n/a
Review Release Date: n/a
Review Release Event: n/a
Review Transfer Date:
Review Withdrawn Fields: n/a
Secure: OPEN
Status: NATIVE
Subject: FDA ADVISORY - FAULTY MANUFACTURING PRACTICES AND POSSIBLE PRODUCT NON-STERILITY (RECALL NO. D-213-6
TAGS: OGEN, ETRD, TBIO, BD, BE, JM, MX, SF
To: BRUSSELS MULTIPLE
Type: TE
Markings: Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 04 MAY 2006